



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/332,803	06/14/99	VOGELS	R 4075US

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EXAMINER

GUZO, D

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/332,803

Applicant(s)

VOGELS, RONALD

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 23-32, 53 and 59-78 is/are pending in the application.
- 4a) Of the above claim(s) 23-32, 53 and 74-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 59-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 4-6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *See Continuation Sheet*.

Continuation of 20. Other: Attachment on deposits of biological materials and Notice to comply with Sequence Rules.

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DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). If the sequences present in the instant application are identical to those in the parent application 09/065,752, applicants need not submit a new CRF but rather must submit in writing a request for the Office to use the CRF filed in the parent to prepare a file for the instant case. Applicants must also state that the CRF is identical to the paper copy of the Sequence Listing filed in the instant case.

Applicant is requested to return a copy of the attached Notice to Comply with the reply.

However, the nature of the non-compliance has not precluded an examination of the application on the merits, the results of which are communicated below.

Applicant's election without traverse of Group I in Paper No. 9 is acknowledged.

Claims 23-32, 53 and 74-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-5, 7-9, 11-12, 15, 59-61, 63-65, 67-68 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Massie et al. (U.S. Patent 5,518,913, issued 5/21/96).

Applicants and Massie et al. (Cited by applicants, see whole document, particularly Figs. 3-4 and Examples 1-3) both recite a method for generating adenoviral vectors comprising welding together (i.e. by homologous recombination in mammalian cells (such as human 293 cells) containing a functional part of an adenoviral E1 region) two nucleic acid molecules (one relatively small and one relatively large and one or both can be linear) comprising partially overlapping sequences capable of combining with one another allowing the generation of a physically linked nucleic acid comprising at least two functional adenoviral ITRs, a functional encapsidation signal and a nucleic acid of interest and wherein the nucleic acid sequences present in the cell do not comprise sequence overlap which could lead to formation of replication competent adenovirus. Applicants and Massie et al. both recite the above method wherein at least one of the nucleic acid molecules comprises an adenovirus ITR which, on one side, is essentially free of other nucleic acid and is made so by using a restriction enzyme.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants claim a method for generating a adenoviral vector comprising using the specific PER.C6 cells deposited at ECACC 96022940. Since the use of the PER.C6 cells deposited at the ECACC is essential for practicing the claimed invention and since the skilled artisan would need to have unrestricted access to the deposited PER.C6 cells, applicants must comply with the deposit rules (37 CFR 1.801-1.809) and must provide a statement that all restrictions on the availability to the public of the deposited material will be irrevocably removed upon granting of a patent on the instant application (See attachment on Deposits of Biological Materials).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 59-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 6, 17 and 62 (and dependent claims) are vague in the use of the phrase "...welding together..." two nucleic acid molecules since this terminology is not art

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recognized in the nucleic acid art and is more appropriate for the metallurgy or mechanical arts. These claims (and claims 3, 12, 59, 68 and 73, and dependent claims) are also vague in that the recitation of nucleic acid sequences from adenoviruses or nucleic acids of interest or ... derivatives and/or analogues thereof." The metes and bounds of the claimed subject matter are vague in that it is unclear what is encompassed by the terms "derivatives" or "analogues" of the specific adenoviral sequences, i.e. do these terms include non-adenoviral sequences, if any, which could perform the same functions as an adenoviral packaging signal or adenoviral ITRs?

Claim 2 is vague in the recitation of sequences which "...allow essentially only one homologous recombination..." event. It is unclear what "essentially only one" homologous recombination event encompasses, i.e. how many other homologous recombination events are encompassed by the phrase "essentially only one" recombination event?

Claims 4, 13, 60 and 69 (and dependent claims) are vague in that they recite the claimed methods performed in a "...functional part, derivative and/or analogue..." of a cell (or specifically a PER.C6 cell). It is unclear what a "functional part" of a cell encompasses and how one would obtain said functional part of the cell and perform the claimed method within said functional part. It is unclear what a "derivative" or "analogue" of a cell is or encompasses.

Claim 59 is vague in the recitation of the phrase "...wherein each said nucleic acid molecules..." because said phrase is convoluted and confusing.

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The terms "relatively small" and "relatively large" in claims 7 and 63 are relative terms which renders the claim indefinite. The terms "relatively small" or "relatively large" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

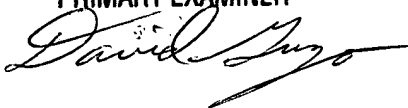
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard A. Schwartz, can be reached on (703) 308-1133. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding or related to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
January 26, 2001

DAVID GUZO
PRIMARY EXAMINER


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Fab Lopez

ATTACHMENT

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready availability thereto by the public if a patent is granted. The depository is to be identified by name and address (See 37 CFR 1.803).
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent (See 37 CFR 1.808(a)(2)).
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 USC 122 (See 37 CFR 1.808(a)(1)).
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 CFR 1.806.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

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States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, date of deposit and the complete taxonomic description.

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7.

Other: _____

Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123

For CRF submission help, call (703) 308-4212

For PatentIn software help, call (703) 557-0400